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In re the Application of:

Garvey et al

TECH CENTER 1600/2900

Application No: 09/516,194

Group Art Unit: 1626

Filed: March 1, 2000

Examiner: R. Gerstl

For:

Use FF/O MAYAY MON (0/14/0/ Nitrosated and Nitrosylated Prostaglandins, Compositions and Methods of Use

Attorney Docket No: 102258.285

**Assistant Commissioner of Patents** 

Washington, DC 20231

### **Provisional Response to Restriction Requirement and** Request for Reconsideration of Restriction Requirement Under 37 C. F. R. §1.143

This response is submitted in reply to the Restriction Requirement dated May 8, 2001, for which a response is due on or before June 8, 2001. No fee is believed to be due; however, the Commissioner is authorized to charge any necessary fees to Deposit Account No. 08-0219 to maintain the pendency of the present application.

#### I. Request for Reconsideration of Restriction Requirement

Under 37 C.F.R. § 1.143, Applicants respectfully request reconsideration of the restriction requirement dated May 8, 2001.

The invention was restricted two-ways as follows:

Group I

Claims 1-9

Compounds of Formula I,

Group II

Claims 10-115

Compositions<sup>1</sup>

Applicants note that claims 42-103 and 107-115 are directed to compositions comprising a parent prostaglandin compound (i.e., prostaglandin compounds that are not nitrosated and/or nitrosylated) in combination with a Snitrosothiol compound, methods of use and kits for the compositions

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The claims in the present application the claims are directed to compounds and composition comprising prostaglandins, methods of use for the compositions and kits for the compositions.

If the compositions, i.e., Group II, are allowable, then all the compounds of Formula I in those compositions would also be allowable, i.e., Group I. In other words, every pending claim that requires a **composition comprising the compounds of Formula I** would be allowable.

Additionally, a search of the prior art for the compositions of Group II, would necessarily encompass a search of the prior art for the compounds of Formula I in those compositions. Thus, the prior art for the compositions of Group II will also be the same prior art for the compounds of Formula I, i.e., Group I.

Applicants would like to direct the Examiner's attention to the search report for the corresponding PCT patent application, serial number PCT/US00/05286, a copy of the search report is attached hereto as Exhibit A. The claims in the PCT patent application and the present application are identical. The Examiner for the PCT patent application examined all the claims together. Also attached as Exhibit B is a copy of the International Preliminary Examination Report dated May 8, 2001, in which claims 1-115 were found to be Novel, Inventive and have Industrial Applicability.

In view thereof, Applicants respectfully submit that the restriction requirement for the present application is improper, as the restriction requirement was not applied in the corresponding PCT application. The claims in the present application and the PCT application are identical.

#### II. Proposed restriction requirement

Applicants respectfully propose that all the pending claims (i.e., claims 1-115) be examined together.

#### III. Provisional Response to Restriction Requirement

Applicants provisionally elect Group II, claims 10-115, drawn to compositions, with traverse.

### IV. Election of Species

In response to the election of species requirement for a composition, Applicants provisionally elect a composition comprising a compound of Formula I and a vasoactive agent.

In response to the election of species requirement for a compound, Applicants provisionally elect the nitrated prostaglandin of Formula A as the compound of Formula I and the  $\alpha$ -blocker, phentolamine as the vasoactive agent, with traverse.

The nitrated prostaglandin of Formula A, has the following structure:

Α

The synthesis of this compound is described in Example 11 of the specification at page 52, line 6 to page 54, line 7.

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Phentolamine, has the following structure:

In response to the election of species requirement for a method of use, Applicants provisionally elect sexual dysfunctions, with traverse.

#### V. Conclusion

Applicants respectfully request that the restriction requirement be withdrawn, and replaced with Applicant's proposed restriction requirement.

An early and favorable consideration and allowance of the pending claims is respectfully requested.

Respectfully submitted

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Dated: June 8, 2001

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